HIV Incidence Surveillance Fact Sheet

1. Why report incidence of HIV infections?

Answer: In the past, biomedical technology has not been able to discriminate between a recent and a long-standing HIV infection; as a result, HIV surveillance has been limited to monitoring prevalence, the proportion of individuals with HIV antibodies regardless of the duration of infection. Recent advances in biomedical technology have resulted in the development of assays that are able to identify recent infections, i.e., infections within the past 6-months. Using this technology, HIV incidence data provide a window into the epidemic at an earlier stage of disease than was previously possible. HIV incidence surveillance data will allow public health officials to monitor the epidemic more completely, to allocate resources, plan, implement, and evaluate prevention programs more effectively.

2. How does HIV incidence surveillance work with routine HIV/AIDS case surveillance?

Answer: HIV incidence surveillance is an extension of the existing national population-based HIV/AIDS Reporting System (HARS). State and local health department partners and the Centers for Disease Control and Prevention (CDC) will use the existing case surveillance infrastructure to collect the information necessary to estimate HIV incidence. This population-based HIV incidence will be estimated from all newly diagnosed HIV cases reported to HARS. In addition to data currently collected in HARS, HIV incidence surveillance requires an aliquot of the remnant blood specimen from the diagnostic HIV test and data on individuals' testing history.

3. How are recent infections identified within a group?

Answer: The serologic testing algorithm for recent HIV seroconversion (STARHS) uses a series of two tests to classify HIV infections as likely or not likely to be recent (i.e., occurring within the past 6-months). After initial infection, a person's antibody level rises in a predictable way. The first test in the algorithm is the standard diagnostic EIA used to detect HIV infection. This EIA is highly sensitive to low levels of HIV antibodies. The second test is less sensitive and measures the antibodies when they get to a higher level. If the standard sensitive test and the second less sensitive test are both above the detection threshold, the infection may be long-standing. If the standard sensitive test is positive and the second les sensitive test is below the threshold, the infection is more likely to be recent.

4. What test will be used to determine if an infection is recent?

Answer: The assay currently used for STARHS to identify recent from long-standing HIV infections for HIV incidence surveillance is the BED HIV-1 Capture EIA. The assay, developed by the CDC, is marketed by Calypte Biomedical Corporation. It was developed specifically for use in identifying recent versus non-recent infections in populations and is performed on serum specimens. This assay has been approved for surveillance use only, results cannot be returned to patients or providers, and the results cannot be used for clinical or diagnostic purposes.

5. Who will be counted in HIV incidence surveillance?

Answer: All cases newly reported to the routine HIV/AIDS Reporting System (HARS) using the adult case report form (aged $\geq$13) will be eligible for STARHS testing and will contribute to the estimate of HIV incidence. Perinatal cases will be counted separately in the incidence estimate.

6. What information is needed to calculate the incidence of new infections?

Answer: We will estimate HIV incidence using the number of infections identified as recent among those individuals who chose to have an HIV test, tested positive, and are newly reported to HARS. This sample along with demographic data, reason for testing, and the history of testing behavior will be used to estimate HIV incidence in the population.

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7. From where will data for the HIV incidence estimate be obtained?

Answer: Three data sources will contribute information needed to calculate the HIV incidence estimate. First, all new cases reported to the HIV/AIDS Reporting System (HARS) on the adult case report form for persons aged ≥13 must be identified.

Second, specimens from persons with a positive HIV diagnostic test will be considered for STARHS testing to be used to estimate incidence. A 0.5 ml aliquot of the HIV diagnostic serum specimen from newly reported HARS cases will be shipped to the CDC STARHS laboratory in New York from private/commercial and public health laboratories for STARHS testing. If remnant serum is not available (e.g., the diagnostic test used an oral screen with an oral confirmation), remnant serum or plasma from other tests used in the care (e.g., CD4, viral load) of HIV-positive persons may be acceptable for use in STARHS testing provided the specimen was drawn within three months of the diagnostic blood draw.

Third, HIV testing history data collected from HIV-positive persons will be used to calculate statistical weights that will allow for the estimation of the number of recent HIV infections in the general population. These testing history data include information on frequency of testing and reason for testing. Currently, testing behaviors are not routinely collected in HARS. However, these data are considered part of routine HIV surveillance. Standard case reporting forms can be revised locally to collect testing behaviors, thus integrating HIV incidence surveillance into routine HIV/AIDS surveillance. Additionally, e-HARS an electronic document-based reporting system will replace HARS. A module to capture testing behaviors will be included in e-HARS. State and local areas will be able to capture testing behaviors in this module as well on a modified case report form.

8. How will HIV incidence be calculated?

Answer: Estimating HIV incidence consists of three steps. First, the data must be stratified by transmission category and HIV testing patterns. Second, an incidence weight must be assigned to every newly diagnosed HIV case. There are different types of weights determined by previous negative HIV test, testing motivation, type of HIV diagnosis (diagnosed with or without AIDS), result of the BED HIV-1 Capture EIA test, and availability of other needed information. Third, the incidence estimate is generated by adding together the weights of all cases within a population. The summation of these weights will be an estimate of the number of recent infections within the population.

9. Will I need additional consent from the person being tested and can I talk about HIV incidence surveillance with the patient?

Answer: The Centers for Disease Control and Prevention (CDC) has determined HIV incidence surveillance to be non-research. As a result, consent for participation in this surveillance system is not required. The Food and Drug Administration (FDA) has agreed that this test can be used for surveillance and as a result consent is not required for use of the BED HIV-1 Capture EIA. This assay can only be used for surveillance and cannot be used for clinical or diagnostic purposes. Providers can discuss HIV incidence with clients. However, results cannot be returned to the patient or to the provider. State and local policies or laws may require consent for the performance of certain tests. You should contact your HIV coordinator to review state and local policies or laws.

10. Where is HIV incidence surveillance being implemented?

Answer: HIV incidence surveillance is being implemented in 34 states, territories and local areas with confidential HIV testing. Within states, territories and local areas, health department officials identify persons for inclusion in HIV incidence surveillance as part of their routine HIV/AIDS case finding and case reporting activities. Cases may be identified from publicly funded Counseling, Testing and Referral sites, private providers, and laboratory reports of confirmed HIV positive persons.

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